IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI CENTRAL DIVISION

J.D., a minor child, by and through his mother and next friend Dana Devantier,	)	
Plaintiff,	)	
v.	)	Case No. 06-4153-CV-C-NKL
GARY SHERMAN in his official capacity as Director of the Missouri Department of Social Services, and MICHAEL DITMORE, M.D., in his official capacity as Director of the Missouri Division of Medical Services	)	
Defendants.	)	

ORDER

Plaintiff J.D. is an eight-year old boy afflicted with a genetic disorder known as Maple Syrup Urine Disease ("MSUD"). A liver transplant will cure J.D. of this disease. On May 30, 2006, the Missouri Medicaid program declined to cover J.D.'s liver transplant. That decision prompted this lawsuit. Pending before the Court is J.D.'s Motion for Preliminary Injunction [Doc. # 3], which seeks an order that Defendant Missouri Medical Services Officials Gary Sherman and Michael Ditmore (collectively, "Missouri Medicaid") provide coverage and payment for J.D.'s liver transplant and all related medical services. For the reasons stated herein, the motion is granted.

I. Overview

Maple Syrup Urine Disease is a volatile and potentially life-threatening metabolic disorder. A person with MSUD is unable to metabolize three of the essential amino acids used by the body to build proteins. As a result, persons with the disease must severely restrict their oral intake of natural proteins, which they replace with daily intake of a special MSUD amino acid formula. When affected individuals become ill with a routine viral or bacterial illness or are unable to maintain their special diet, they are at risk for severe metabolic decompensation with neurological deterioration, brain swelling, coma, permanent brain injury and death. Even with careful dietary management, metabolic decompensation can occur. J.D. has been hospitalized on numerous occasions for control of his fluids and metabolism and, even with optimal medical management, will always be at risk for serious injury or death.

Dr. David Nile, a pediatrician, and Dr. Dorothy Grange, a geneticist, have both treated J.D. since his birth. Drs. Nile and Grange believe J.D.'s liver transplant is medically necessary. J.D. was also examined by Dr. Ross Shepherd. Dr. Shepherd is the medical director of pediatric liver transplant at the St. Louis Children's Hospital at Washington University Medical School. Dr. Shepherd's examination was done at the request of Dr. Nile "to assess for the Missouri Division of Medical Services whether liver transplantation would be curative of J.D.'s Classical Maple Syrup Urine Disease . . . and if so, to make recommendations as to the most appropriate center to perform such a transplant." [Shepherd Decl. ¶ 6.] Dr. Shepherd agreed with the treating physicians' conclusion that J.D.'s liver transplant is medically necessary and recommended that J.D.

have the procedure done at the Children's Hospital of Pittsburgh, which has experience with MSUD-related liver transplants. A fourth physician, Dr. George Mazariegos, director of pediatric transplant surgery at the Children's Hospital of Pittsburgh, evaluated J.D. and also agreed that a liver transplant is medically necessary. Dr. Mazariegos noted that "[a] medically managed dietary and pharmaceutical regimen for [J.D.] is not an equivalent alternative treatment to liver transplantation. Although medical management has improved the survival rate of MSUD patients, it does not achieve normal neurological outcomes for these patients. Strict adherence to such a regimen will not prevent [J.D.] from suffering progressive neurological impairment as a result of the chronic effects of MSUD." [Mazariegos Decl. ¶ 10.]

The United Network for Organ Sharing ("UNOS") administers the national Organ Procurement and Transplantation Network established by Congress in 1984. According to Dr. Mazariegos, "UNOS generally ranks pediatric liver transplant candidates in descending order according to a mortality risk score." [Mazariegos Decl. ¶ 12.] The ranking system spans from scores of negative 10, which indicate the patient is not critically in need of a transplant, to 25 or higher, which indicate the patient is a transplant priority. Patients may also be classified as Status IA and IB, which means the patient is in critical need of a transplant. UNOS endorses pediatric liver transplants for candidates with metabolic diseases that have severe consequences but do not put them in the category of liver failure. "Because of the neurological burden of their diseases, young children with classical MSUD have qualified . . . for high prioritization on the ranking

system with scores of 30 or more points." [Mazariegos Decl. ¶ 12.]

On or about March 23, 2006, a representative of Missouri's Medicaid program notified the Children's Hospital of Pittsburgh that J.D. had been approved for a Medicaid transplant.[1] Missouri Medicaid then sent the hospital forms that would allow Children's Hospital to become an approved provider. Between March 23, 2006 and April 27, 2006, negotiations took place between Missouri Medicaid and Children's Hospital of Pittsburgh. On or about April 17, 2006, Missouri Medicaid offered to pay the hospital a maximum amount of $100,000 for the first 45 days from the date of the transplant procedure and a per diem of approximately $852.90 up to $130,000 for days 46-80. Children's Hospital of Pittsburgh rejected Missouri Medicaid's offer and, on April 21 and April 26, 2006, proposed a fee equivalent to that paid by the Pennsylvania Medicaid program for a liver transplant. Pennsylvania Medicaid pays $158,000 for the first 62 days after the transplant and an additional $2,300 per day if hospitalization beyond 62 days is required. Children's Hospital of Pittsburgh also recommended that Missouri Medicaid pay approximately $22,460.80 in professional fees. On April 27, 2006, Missouri Medicaid informed the hospital that all pre-transplant services would be paid by Healthcare USA, a Medicaid managed care plan. Missouri Medicaid, however, made no counteroffer to the hospital for the transplant procedure. Approximately two weeks later,

[1]At oral argument the Defendants claimed that no such notification occurred. However, in response to the Motion for Preliminary Injunction, they did not include an affidavit on this issue or otherwise deny the communication.

after failing to agree on the price of J.D.'s liver transplant, Missouri Medicaid informed Children's Hospital of Pittsburgh that it considered the transplant an elective option rather than a medical necessity. Missouri Medicaid then asked the hospital a series of questions related to the MSUD transplants performed at the hospital and the health status of the patients who have already undergone the procedure. The hospital answered Missouri Medicaid's questions by email on May 23, 2006. Approximately one week later, Children's Hospital of Pittsburgh received a denial letter for J.D.'s liver transplant from Missouri Medicaid.

Dr. Michael D. Wilson, a physician consultant with Missouri Medicaid, "took part in making the decision to deny Medicaid coverage for [J.D.'s liver transplant]." [Wilson Decl. ¶ 3.] Though he never evaluated J.D. in person, he did review the other physicians' notes and relevant articles in medical journals. Dr. Wilson determined that "JD's condition has been well managed and that the dietary treatment of MSUD, especially when the condition is well-managed, has good outcomes." [Wilson Decl. ¶ 7.] Based on this and Dr. Wilson's knowledge of the risks associated with liver transplants, Dr. Wilson concluded that J.D.'s liver transplant was not medically necessary. Dr. Wilson insists that "[t]he potential cost of transplant did not have an effect on the decision that [J.D.'s liver transplant] is not medically necessary." [Wilson Decl. ¶ 10.]

II. Discussion

In deciding J.D.'s Motion for Preliminary Injunction, the Court considers four factors: (1) the probability that J.D. will succeed on the merits, (2) the threat to J.D. of

irreparable harm should the Court not grant his motion, (3) the balance between the harm to J.D. and the injury that granting the injunction will have on other interested parties, and (4) the public interest. *Lankford v. Sherman*, 451 F.3d 496, 503 (8th Cir. 2006). Because he seeks the injunction, J.D. bears the burden of proving these factors, none of which is dispositive. *Id*. The Court is required to balance all of the factors in deciding whether the injunction should issue. *Id*. ("The district court has broad discretion when ruling on preliminary injunctions.").

A. J.D.'s Likely Success on the Merits

The Medicaid Act is a federal program created to help states provide medical services to their low-income populations. *Schweiker v. Hogan*, 457 U.S. 569, 572, 102 S. Ct. 2597 (1982). Once a state elects to participate in Medicaid, it must comply with all federal statutory and regulatory requirements. *Lankford*, 451 F.3d at 504. One such requirement is that participating states provide medical services to the "categorically needy," a group that includes children. *Id*.; 42 U.S.C. § 1396a(a)(10)(A). With the exception of certain mandated medical services,[2] participating states may determine what medical services they will provide. 42 U.S.C. §§ 1396a(a)(10), 1396d(a). If a state chooses to provide an optional medical service, then it must comply with all federal statutory and regulatory requirements as if the service were mandatory. *Lankford*, 451

[2] States must provide the following medical services: inpatient hospital, outpatient hospital, laboratory and x-ray, nursing facility, physician, nurse-midwife, and nurse-practitioner. 42 U.S.C. §§ 1396a(a)(10), 1396d(a).

F.3d at 504.

J.D. argues that he is likely to succeed on the merits of his claim because Missouri Medicaid's denial of his transplant request violates (1) the "early and periodic screening, diagnostic, and treatment services" ("EPSDT") requirement, (2) the reasonable standards requirement and (3) the transplant requirement that similarly situated individuals be treated alike. As a threshold matter, for J.D. to prevail on any of these three theories, J.D.'s liver transplant must be medically necessary.

1. Medical Necessity

In *Weaver v. Reagen*, the Eighth Circuit Court of Appeals held that a medical necessity determination "rests with the individual recipient's physician and not with clerical personnel or government officials." 886 F.2d 194, 199 (8th Cir. 1989). This presumption in favor of treating physicians, however, may be overcome. *Id.* at 200.

Four doctors have evaluated J.D. in person and determined that a liver transplant is medically necessary. First, Dr. David Nile (J.D.'s treating pediatrician) and Dr. Dorothy Grange (J.D.'s treating geneticist), both of whom have treated J.D. since birth, determined that a liver transplant was medically necessary to cure J.D.'s MSUD. Thereafter, Dr. Ross Shepherd, medical director of pediatric liver transplant at the St. Louis Children's Hospital at Washington University Medical School, evaluated J.D. Dr. Shepherd's examination was done at the request of Dr. Nile "to assess for the Missouri Division of Medical Services whether liver transplantation would be curative of J.D.'s Classical Maple Syrup Urine Disease . . . and if so, to make recommendations as to the most

appropriate center to perform such a transplant." (Shepherd Decl. ¶ 6.) Dr. Shepherd agreed with Drs. Nile and Grange that J.D.'s liver transplant was medically necessary. Dr. Shepherd recommended the transplant be performed at the Children's Hospital of Pittsburgh, which has experience with MSUD-related liver transplants. A fourth physician, Dr. George Mazariegos, director of pediatric transplant surgery at the Children's Hospital of Pittsburgh, also evaluated J.D. in person and agreed that a liver transplant is medically necessary. No evidence in the record suggests that any doctor, after evaluating J.D. in person, has concluded that a liver transplant is not medically necessary.

In addition to the opinions of J.D.'s treating physicians, general support for the proposition that liver transplantation is a medically necessary procedure for children with MSUD is found in the practices of the United Network for Organ Sharing. Notwithstanding the fact that life long dietary management is an option for MSUD sufferers, the United Network for Organ Sharing has ranked children with classical MSUD as high priority liver transplant candidates because of the neurological burden and risks of the disease.

In support of its position that J.D.'s liver transplant is not medically necessary, Missouri Medicaid cites (1) information procured from medical websites stating that "[t]he mainstay treatment for MSUD is dietary restriction of amino acids" [Defs' Resp. at 4]; (2) statistics showing the survival rate for persons undergoing liver transplants is less than 100% [Defs' Resp. at 5]; and (3) the uncertainty of the long-term outcomes for

MSUD patients who undergo liver transplant procedures [Defs' Resp. at 6].

Missouri Medicaid also noted that alternative treatments, such as dietary management, exist to manage individuals suffering from MSUD. Missouri Medicaid does not dispute, however, that only a liver transplant actually cures MSUD.

In addition, Missouri Medicaid offers the declaration of Dr. Michael D. Wilson, a physician consultant with Missouri Medicaid, who "took part in making the decision to deny Medicaid coverage for [J.D.'s liver transplant]." [Wilson Decl. ¶ 3.] Dr. Wilson never evaluated J.D. in person, but he did review the other physicians' notes and relevant articles in medical journals. Dr. Wilson determined that "JD's condition has been well managed and that the dietary treatment of MSUD, especially when the condition is well-managed, has good outcomes." [Wilson Decl. ¶ 7.] Based on this and Dr. Wilson's knowledge of the risks associated with liver transplants, Dr. Wilson and the other decision makers concluded that J.D.'s liver transplant was not medically necessary. Dr. Wilson insists that "[t]he potential cost of transplant did not have an effect on the decision that [J.D.'s liver transplant] is not medically necessary." [Wilson Decl. ¶ 10.]

It is noteworthy that a Missouri Medicaid representative notified Children's Hospital of Pittsburgh that J.D.'s liver transplant had been approved. For several weeks following the approval, Missouri Medicaid and the hospital negotiated over the price of the transplant. Ultimately, the parties were unable to agree on a price. Only after the negotiations ended did Missouri Medicaid indicate to the hospital that it did not consider J.D.'s transplant medically necessary. Dr. Wilson insists these two events–the close of

the failed negotiations and Missouri Medicaid's determination that J.D.'s transplant was not medically necessary–are unrelated. However, Missouri Medicaid has offered no evidence that it routinely communicates approval to, and negotiates price with, an institution prior to deciding whether a transplant is a medical necessity.

Missouri Medicaid has not overcome the presumption in favor of the treating physicians' conclusion that J.D.'s liver transplant is medically necessary. Notwithstanding the fact that the survival rate for persons undergoing liver transplants is less than 100% and that compliance with dietary requirements can help prevent MSUD-related deaths, the Court finds the unanimous opinion of every doctor who actually examined J.D. persuasive. Given the ever present risk of irreparable brain injury, and the limitations J.D. currently suffers, there is a substantial difference between curing and managing J.D.'s MSUD. On the record before the Court, the Court finds that J.D.'s liver transplant is medically necessary. Therefore, it is likely that J.D. will ultimately succeed on the merits of this issue.

2. Medicaid's EPSDT Requirements

Participating states are required to provide "early and periodic screening, diagnostic, and treatment services" ("EPSDT") for children under age 21. 42 U.S.C. § 1396d(a)(4)(B); *Pediatric Speciality Care, Inc. v. Arkansas Dep't of Human Servs.*, 293 F.3d 472, 479 n. 5 (8th Cir. 2002). The Fourth and Eleventh Circuit Courts of Appeals have held that the EPSDT requirements mandate coverage of medically necessary transplants for children. *Pereira v. Kozlowshi*, 996 F.2d 723, 727 (4th Cir. 1993);

Pittman v. Secretary, Florida Dep't of Health & Rehabilitative Servs., 998 F.2d 887, 891-92 (11th Cir. 1993). The Court believes that the reasoning of the *Pittman* case is particularly persuasive;[3] however, the Court need not decide whether the Eighth Circuit would reach the same conclusion because another provision in federal Medicaid law demonstrates that it is likely that J.D. will succeed on the merits of his claim

3. Medicaid's Reasonable Standards Requirement

The Medicaid Act requires a participating state to employ "reasonable standards . . . for determining . . . the extent of medical assistance under the plan which . . . are consistent with the objectives of this subchapter." 42 U.S.C. § 1396a(a)(17). This reasonable standards requirement restricts a participating state's discretionary flexibility in determining medical assistance under its plan. *Lankford*, 451 F.3d at 506 (citing *Beal v. Doe*, 432 U.S. 438, 444, 97 S. Ct. 2366 (1977)). Furthermore, though Missouri Medicaid is not required to cover organ transplants, "once a state has adopted a policy to cover a category of organ transplants, it may not arbitrarily or unreasonably deny services to an otherwise eligible Medicaid recipient." *Meusberger*, 900 F.2d at 1282. Indeed, the same legislative history relied on by the Eighth Circuit, in *Ellis*, provides as follows:

> Organ transplant technical.–Under current law, States must offer certain mandatory services, such as inpatient hospital and physicians's services, each of which must be sufficient in amount, duration, and scope to

[3]While the Eighth Circuit in *Ellis v. Patterson*, 859 F.2d 52 (8th Cir. 1988), found that states have the discretion to deny organ transplants to children, Congress amended the Medicaid statute in 1989, to mandate medically necessary treatments for children under the age of 21, even if the treatment is not covered by the state plan. *See* 42 U.S.C. 1396d(r).

> reasonably achieve its purpose. States may not arbitrarily deny or reduce the amount, duration, or scope of a mandatory service solely because of an individual's diagnosis, type of illness, or condition. To assure that coverage decisions for organ transplants are based on clear principles consistently applied, and not on political or media consideration, section 9507 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), P.L. 99-272, [the section herein at issue, 42 U.S.C. § 1396b(i)(1)] requires that a State which covers organ transplant procedures set forth under its Medicaid plan written standards respecting the coverage of such procedures. Under these standards, similarly situated individuals must be treated alike.
>
> The Committee wishes to clarify that the organ transplant procedures which a state covers, and the hospital, physician, and other services these procedures entail, must be sufficient in amount duration, and scope to reasonably achieve their purpose.
>
> *For example, if a State covers liver transplants for patients with one medical condition but not for patients with another, and if liver transplant is medically indicated and not experimental with respect to each condition, the State's plan would be out of compliance with the amount, duration, and scope requirement.*

H.R.Rep. No. 100-391, 100th Cong., 1st Sess. (1987), U.S.Code Cong. & Admin. News 1987, 2313-1, 2313-352 (emphasis added).

It is undisputed that, because he is a child, J.D. is "an otherwise eligible Medicaid recipient." Missouri Medicaid's plan provides that benefits "may be provided" for liver transplants, but that "[e]ach request for coverage will be handled on a case-by-case basis." 13 CSR 70-2.200(2). Despite its "case-by-case" provision, Missouri Medicaid has unequivocally adopted a policy to provide benefits for the category of liver transplants. Thus, in order to succeed on the merits, J.D. must prove that Missouri Medicaid's decision to deny his liver transplant was unreasonable. *Meusberger*, 900 F.2d at 1282.

Because Missouri Medicaid covers the category of liver transplants and he is an otherwise eligible Medicaid recipient, J.D. may show that its decision not to cover his transplant was unreasonable by showing that his transplant is medically necessary. *Lankford*, 451 F.3d at 511 ("[A] state's failure to provide Medicaid coverage for non-experimental, medically-necessary services within a covered Medicaid category is both per se unreasonable and inconsistent with the stated goals of Medicaid."). As noted in Section II(A)(1), J.D. has shown that his liver transplant is medically necessary. Accordingly, J.D. is likely to succeed on his claim that Missouri Medicaid's decision not to cover his liver transplant violated Medicaid's Reasonable Standards requirement.

B. J.D. Will Suffer Irreparable Harm

To show irreparable harm J.D. must establish that without a liver transplant he faces a meaningful risk of serious injury or death. *Frye v. Minnesota Dep't of Corrections*, 2006 WL 1472783 at *2 (D. Minn. 2006). Dr. Grange, J.D.'s treating geneticist, noted that "MSUD is a volatile and potentially life threatening disorder. When affected patients become ill with even a routine viral or bacterial illness and/or are unable to maintain their special diet and drink the MSUD formula for whatever reason, they are at risk for severe metabolic decompensation with neurological deterioration, brain swelling, coma, permanent brain injury, and death. Despite careful management of the diet, metabolic decompensation can still occur." [Grange Decl. ¶ 9.] Moreover, even with continued medical management, J.D. "will always remain at risk for seriously devastating consequences or death." [Niles Decl. ¶ 9.] This on-going danger of

metabolic decompensation evidences a meaningful risk to J.D.'s health should the preliminary injunction not issue; accordingly, J.D. has shown irreparable harm sufficient to justify a preliminary injunction. *Kai v. Ross*, 336 F.3d 650, 656 (8th Cir. 2003) (noting that danger to plaintiffs' health is evidence of irreparable injury); *Henderson v. Bodine Aluminum, Inc.*, 70 F.3d 958, 961 (8th Cir. 1995) ("It is hard to imagine a greater harm than losing a chance for potentially life-saving medical treatment.").

C. The Balance of Harm and the Public Interest

Missouri Medicaid asserts two theories for why the balance of harm and the public interest considerations should be found in its favor. First, Missouri Medicaid argues that the public will benefit from full consideration of J.D.'s claims, which will essentially be bypassed if the preliminary injunction is granted.[4] Nothing, however, prevents Missouri Medicaid from continuing to litigate this matter if it believes final resolution of the question is in the public's interest. However, because there is such a strong likelihood that J.D. will be successful on the merits, further delay is not warranted given the nature of the harm to which J.D. is exposed.

Second, Missouri Medicaid argues that granting this injunction would require it to fund an expensive procedure and limit its ability to use its money for other things. As a preliminary matter, it is not clear that the cost of J.D.'s curative surgery would be greater than the sum of the recurring treatments J.D. would continue to receive in an effort to

[4]In response to J.D.'s Motion for Preliminary Injunction, the Defendants were able to present all the evidence they relied on to reject J.D.'s liver transplant request.

manage his MSUD in future years. But, even if it were obvious that the state could save some money by treating, as opposed to curing J.D., the fiscal harm suffered by Missouri Medicaid is outweighed by the harm to J.D. should he not receive a liver transplant. *Todd v. Sorrell*, 841 F.2d 87, 88 (4th Cir. 1988) (holding that financial harm to state was negligible in comparison to potentially fatal harm to plaintiff); *Nemnich v. Stangler*, 1992 WL 178963 at *3 (W.D. Mo. 1992) (holding that "harm to the plaintiffs' [lives] and health clearly outweighs any fiscal harm the state may suffer."). More importantly, if Medicaid law requires the transplant, saving money in this case is not an option for the State of Missouri.

III. Conclusion

Having balanced J.D.'s likelihood of success and his risk of irreparable harm against the harm to the Defendants, and having considered the public interest, the Court concludes that the preliminary injunction should issue.

Accordingly, it is hereby

ORDERED that J.D.'s Motion for Preliminary Injunction [Doc. # 3] is GRANTED.

Defendants Sherman and Ditmore are ordered to provide or ensure Missouri Medicaid coverage and payment for a liver transplant for J.D. at the Children's Hospital of Pittsburgh[5] and for all medical services related to such transplants.

[5]The Defendants have not presented any evidence that this is not the appropriate facility if a liver transplant is ordered.

s/ Nanette K. Laughrey
NANETTE K. LAUGHREY
United States District Judge

DATE: October 27, 2006
Jefferson City, Missouri